

DETAILED ACTION

Restriction/Elections

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 28-31, 33-34, and 36-43 drawn to a composition containing a film former in class 424, subclass 451.
- II. Claims 22-24 and 32, drawn to a method of making a film, classified in class 106, subclass 162.2.
- III. Claims 25-27 and 35, drawn to the method of making a capsule, drawn to a method of making a capsule, classified in class 53, subclass 454.

Inventions I and III, as well as I and II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, since invention I can be used to make the different products that result from the methods of inventions II and III, invention I is distinct from both inventions II and III. In addition, the inventions would require different fields of search.

Inventions II and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as a support for cells. The inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants. In addition, the inventions would require different fields of search and have different status in the art.

Election

Claims 1-21, 28-31, 33-34, and 36-43 are generic to the following disclosed patentably distinct species: compositions containing kappa-2 carrageenan and compositions containing polymannan gum. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record. The applicant is required to elect a single disclosed species such that each component is distinctly specified.

If Invention I is elected then an election must be made for each of the following:

- Presence or absence of second film former (e.g. claims 2, 5-8, 31, 33-34, 37, and 41)
- Presence or absence of bulking agent (e.g. claims 38 and 41-42)
- Presence or absence of plasticizer (e.g. claims 36 and 40)
- Film (not a fillable form) or fillable form

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

Art Unit: 1654

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoiner in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention or species, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

Art Unit: 1654

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention and species.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions (or species) are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions (or species) to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions (or species)

Art Unit: 1654

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention (or species).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0563, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm
Examiner
Art Unit 4173

CH

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4173